



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0547]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)--(OMB Control Number 0910-NEW)

I. Background

In 1998, the U.S. Food and Drug Administration's National Retail Food Team initiated a 10-year voluntary survey to measure trends in the occurrence of foodborne illness risk factors--preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the retail level. Specifically, the survey included data collection inspections of various types of retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources.
- Poor Personal Hygiene.
- Inadequate Cooking.
- Improper Holding/Time and Temperature.

- Contaminated Equipment/Protection from Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008) (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

The research obtained from these studies provides FDA a solid foundation for developing a national retail food program model that can be used by Federal, State, local, and tribal agencies to:

- Identify essential food safety program performance measurements;
- Assess strengths and gaps in the design, structure, and delivery of program services;
- Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors; and
- Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

Using this 10-year survey as a foundation, FDA is proposing to conduct a new voluntary survey encompassing annual data collections over a 10-year period. The survey will determine the following for each facility type included in the study:

- The foodborne illness risk factors that are in most need of priority attention during each data collection period;
- Trends of improvement or regression in foodborne illness risk factor occurrence over time; and

- The impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The results of the proposed study will be used to:

- Formulate Agency retail food safety policies and initiatives;
- Identify retail food work plan priorities and allocate resources to enhance retail food safety nationwide;
- Generate nationally representative estimates of the progress being made to reduce the occurrence of foodborne illness risk factors in retail and foodservice establishments; and
- Recommend best practices and targeted intervention strategies to assist the retail and foodservice industry and state, local, and tribal regulators with reducing foodborne illness risk factors.

The statutory basis for FDA conducting this survey is the Public Health Service Act (the PHS Act) (42 U.S.C 243, section 311(a)) (Also 21 CFR 5.10(a)(2) and (4)), which requires that FDA provide assistance to state and local governments relative to the prevention and suppression of communicable diseases. In addition, the PHS Act requires that FDA cooperate with and aid state and local authorities in the enforcement of their health regulations and provide advice on matters relating to the preservation and improvement of public health. Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and Economy Act (31 U.S.C. 1535) require that FDA provide assistance to other Federal, State, and local governmental bodies.

In early 2013, FDA will conduct a pilot data collection to practice the use of the data collection form and methods and test exportation of the pilot data into a central repository.

Following the pilot, the Agency plans to conduct annual data collections beginning in 2013 with

the initial data collection for select restaurant facility types, followed by the initial data collection for select institutional foodservice facility types in 2014 and select retail food store facility types in 2015. The results of the initial data collection for each of the facility types will serve as the baseline measurement from which trends will be analyzed. Two additional data collection periods for each of the facility types are planned at 3-year intervals after the initial data collection for purposes of analyzing trends.

Table 1.--Summary of Data Collection Timeframes¹

Industry Segment	Facility Types Included in the Survey	Year for Initial Data Collection (Baseline Measurement)	Second Data Collection Period	Third and Final Data Collection Period
Restaurants	Full Service Restaurants	2013	2016	2019
	Fast Food Restaurants			
Institutional Foodservice	Hospitals	2014	2017	2020
	Nursing Homes			
	Elementary Schools (K-5)			
Retail Food Stores	Deli Departments/Stores	2015	2018	2021
	Meat & Poultry Departments/Markets			
	Seafood Departments/Markets			
	Produce Departments/Markets			

¹Data collections for each of the facility types within an industry segment will be conducted using a 3-year interval period. Initial data collection will serve as the baseline. Subsequent collections will provide the data needed to analyze trends.

A description of the facility types included in the proposed survey is included in table 2:

Table 2.--Description of the Facility Types Included in the Survey

Industry Segment	Facility Type	Description
Restaurants	Full Service Restaurants	Establishments where customers place their order at their table, are served their meal at the table, receive the service of the wait staff, and pay at the end of the meal.
	Fast Food Restaurants	Also referred to as quick service restaurants and defined as any restaurant that is not a full service restaurant.
Institutional Foodservice	Hospitals	Foodservice operations that serve patients, staff, and hospital visitors in a traditional hospital setting. Individuals who are acutely ill to those who are immunocompromised are a target population for data collection.
	Nursing Homes	Foodservice operations that serve highly susceptible populations living in a group care setting. The elderly (55+ years) is the target population for the data collection. Also includes assisted living facilities.
	Elementary Schools (K-5)	Foodservice operations that serve students from one or more grade levels from preschool through grade 5. Young children are a target population for the data collection.

Table 2.--Description of the Facility Types Included in the Survey

Retail Food Stores	Deli Departments/ Stores	Departments in retail food stores where potentially hazardous foods (time/temperature control for safety foods) such as luncheon meats and cheeses are sliced for the customer and where sandwiches and salads are prepared on site or received from a commissary in bulk containers, portioned, and displayed. Freestanding cheese shops are categorized as delis. Parts of the deli may also include: <ul style="list-style-type: none"> • Salad bars and other food bars maintained by the deli department manager; • Areas where meat or poultry are cooked and offered for sale as ready-to-eat; • Pizza stands; and • Limited bakery operations attached to or adjacent to the deli.
	Meat and Poultry Departments/Markets	Meat and poultry departments in a retail food store, as well as any freestanding meat market or butcher shop that sells raw meat or poultry directly to the consumer.
	Seafood Departments/ Markets	Seafood departments in retail food stores and freestanding seafood markets that sell seafood directly to the consumer including the preparation and sale of raw and/or ready-to-eat seafood. In-store sushi bars are considered part of the seafood department for the purposes of the data collection.
	Produce Departments/ Markets	Areas or departments where produce is cut, prepared, stored, or displayed. A produce department may include salad bars that are managed by the produce manager, as well as juicers.

A geographical information system database containing a listing of businesses throughout the United States will be used as the establishment inventory for the data collections. FDA's Center for Food Safety and Applied Nutrition (CFSAN) Biostatistical Branch, in collaboration with the FDA National Retail Food Team, will perform a series of filtering processes of the various database food establishment categories to ensure establishments are correctly classified and considered eligible to participate in the survey based on the descriptions in table 2.

To further determine the pool of establishments eligible for selection, an effort will be made to exclude operations that handle only prepackaged food items or conduct low-risk food preparation activities. The FDA Food Code contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The vast majority of selected establishments are to be chosen from risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's CFSAN personnel in the application and interpretation of the FDA Food Code (Ref. 5). The geographical distribution of Specialists throughout the United States allows for a broad sampling of facility types in all regions of the United States; therefore, establishments will be randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of each of the Specialists' home locations.

The pilot will include approximately 4 data collection inspections for each of the approximately 25 Specialists, or a total of 100 inspections. In order to obtain a sufficient number of observations to conduct statistically significant analysis, the FDA CFSAN Biostatistical Branch has determined, based on the previous 10-year foodborne illness risk factor study that was performed, that approximately 400 data collection inspections of each facility type are needed during the initial and subsequent data collection periods. The sample for each data collection period will be evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments will be selected for each Specialist for cases in which the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist will verify with the jurisdiction that the facility has been

properly classified for the purposes of the study and is still in operation. The Specialist will also ascertain whether the selected facility is under legal notice from the state or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection and a substitute establishment will be used. An invitation will be extended to the state or local regulatory authority to accompany the Specialist on the data collection visit.

A standard data collection form will be used by the Specialists during each inspection. The form is divided into three sections: Section 1--Establishment Information; Section 2--Regulatory Authority Information; and Section 3--Foodborne Illness Risk Factor and Food Safety Management System Assessment. Section 3 includes three parts (parts A–C) for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards (part A); the industry food safety management being implemented by the facility (part B); and the frequency of food employee hand washing (part C).

In completing Section 1--Establishment Information of the form, Specialists will ask a standardized set of questions to the establishment owner or person in charge. In completing Section 2--Regulatory Authority Information, the Specialist will ask a standardized set of questions to the program director (or other designed personnel) of the state or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment. The information for completing Section 3, part A of the form will be collected from the Specialists' direct observations of food employee behaviors and practices, supplemented by infrequent, nonstandardized questions to industry personnel when clarification is needed of the food safety procedure or practice being observed. For Section 3, part B of the form, Specialists will ask industry management a standardized set of questions to obtain information on the extent to

which the food establishments have developed and implemented food safety management systems. Section 3, part C of the form will involve only direct observations of hand washing frequency by the Specialists. No questions will be asked in the completion of this part of the form.

In the Federal Register of June 19, 2012 (77 FR 36544), FDA published a 60-day notice requesting public comment on the proposed collection of information. There were five comments received:

(Comment 1) Jane Public commented that she does not see the usefulness of the study. She also commented that most foodborne illness resulting from food from unsafe sources was caused by agribusiness. She commented that having a Web site on which the public or doctors treating the sick and deceased can post information about foodborne illness would be more effective and targeted than the data collection being proposed by FDA.

(Response) FDA believes that many of the comments made by this submitter are unrelated to the proposed data collection. Relative to the suggestion to have a Web site on which the public or doctors treating the sick or deceased can post information about foodborne illness, surveillance systems like this are already used in the United States to provide information about the occurrence of foodborne disease including, but not limited to, the following: Foodborne Disease Active Surveillance Network (FoodNet); National Antimicrobial Resistance Monitoring System--enteric bacteria (NARMS); National Electronic Norovirus Outbreak Network (CaliciNet); National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet); National Notifiable Diseases Surveillance System (NNDSS); National Outbreak Reporting System (NORS); Environmental Health Specialists Network (EHS-Net); and the Public Health Laboratory Information System (PHLIS). While each surveillance system plays an

important role in detecting and preventing foodborne disease and outbreaks, surveillance statistics reflect only a fraction of the cases that occur in the community. This is because foodborne illnesses are largely underdiagnosed and underreported. In addition, surveillance statistics are, by nature, reactive, meaning information is obtained on foodborne illness that has already occurred. In contrast, the data collection proposed by FDA is proactive in nature because it seeks to collect data on the behaviors and practices that could lead to foodborne illness or deaths if not controlled. Using this data, FDA will formulate and implement intervention strategies to proactively reduce foodborne illness risk factors that lead to illness or death if not controlled. For these reasons, FDA does not agree with the submitter that another surveillance-type reporting system would be more effective or targeted than the data collection being proposed by FDA.

(Comment 2) The Food Marketing Institute (FMI) commented that FDA appears to have underestimated the amount of time needed at 15 minutes per event. The commenter states that based on the retail industry's experience during the last survey (2008), the time spent collecting and monitoring data points took up 120 minutes per event per retail grocer, and this caused an undue interruption to business operations and passed on unnecessary costs to those surveyed.

(Response) OMB's regulations at 5 CFR 1320.3(h) define the term "information." Numbered paragraphs under (h) list categories of data that are not "information," and thus do not require OMB approval under the PRA. Under paragraph (h)(3), "[f]acts or opinions obtained through direct observation by an employee or agent of the sponsoring agency or through nonstandardized oral communication in connection with such direct observations," is not "information collection" subject to OMB approval under the PRA. Thus, the estimate of burden is not required to account for the duration of the entire inspection since the data collector's

questions will largely be nonstandardized, oral communication in connection with his or her direct observations.

In contrast, information collected in Sections 1 and 2 and Section 3, part B of the data collection form is not available to the data collectors by direct observation together with nonstandardized, oral communication and can only be obtained by asking the establishment's representatives to respond to a set of standardized questions. Thus, the burden is accurately calculated based solely on the time it will take for the data collectors to interview the respondents to complete these specific sections of the form. However, in consideration of FMI's comment and recent data collection training that was conducted with FDA's National Retail Food Team in September 2012, FDA believes that the original burden for the respondents that was published in table 1 of the 60-day notice may have been underestimated. For this reason, FDA is increasing the burden estimate for each respondent to 30 minutes per response.

(Comment 3) FMI commented that FDA is not aligned with CDC in the development of the study. According to CDC data, most foodborne illness outbreaks occur in restaurants (39 percent compared to <1 percent foodborne illness events occurring in grocery stores as well as 21 percent compared to <1 percent actual foodborne illnesses occurring in grocery stores). Based on the data, FMI believes the study seems to put an unnecessary burden on retail grocery stores as retail grocery stores will be surveyed at a 4:1 ratio. The study should be more balanced between the restaurants and grocers.

(Response) FDA has kept and will continue to keep key CDC staff informed of the plans for and results of the Risk Factor Study so that areas in which our concurrent studies reinforce or run counter to one another can be analyzed and appropriate prevention-based messages developed.

The proposed sample size for each facility type is not intended to mirror the respective burden of foodborne illness caused by each type, but rather represents the minimum number of inspections needed to obtain the number of observations needed to draw statistically significant conclusions. If FDA reduced the number of establishments inspected for the retail food store facility types, it is likely FDA would not obtain the number of observations needed to draw statistically valid conclusions or have the desired confidence level in the data that is obtained.

The restaurant industry segment includes two facility types, institutional foodservice includes three facility types, and the retail food store industry segment includes four facility types. While the total number of data collection inspections in retail food store segment will be higher than that for the restaurant segment, the number of data collection inspections for each facility type will be the same.

(Comment 4) FMI believes the proposed study fails to meet FDA's Information Quality Guidelines and the requirements of the Data Quality Act because its structure will not provide information of utility to the public or the Agency as it is disproportionately focused on retail food stores when statistics indicate that far more foodborne illness events occur in restaurants.

(Response) Information dissemination is an important part of FDA's mission to promote and protect the public health. FDA recognizes that public access to high quality information is critical to achieving this mission and public input, in turn, improves the quality of the information we disseminate. Because of the nature of this information, our goal has been and remains to ensure that all the information we disseminate meets the high standards of quality (including objectivity, utility, and integrity) described in the OMB and HHS Guidelines and the Data Quality Act (DQA).

To that end, FDA does not agree with FMI's comment that the proposed information collection fails to meet FDA's Information Quality Guidelines and the requirements of the DQA. The sample size in the proposed information collection is not intended to mirror the respective burden of foodborne illness caused by each facility type. Rather, it represents the minimum number of inspections needed for each facility type in order to obtain a sufficient number of observations to draw statistically significant conclusions. If FDA were to reduce the sample size of the retail food store facility types to be more reflective of the burden of foodborne illness caused by these entities, the quality of the data would be compromised and its utility would be severely limited. This is because it would be unlikely that FDA could obtain the number of observations needed to draw statistically valid conclusions or have the desired confidence level in the conclusions we are able to make.

(Comment 5) The American Meat Institute Foundation (AMIF) commented that they support FDA's proposed survey of selected retail and foodservice facility types. According to AMIF, the survey findings will have practical utility by enhancing the knowledge of foodborne illness risk factors in these types of facilities, informing decisions for developing and implementing risk mitigation strategies, and guiding food safety resource allocation. The followup data collection periods will be useful tools to track trends and benchmark improvements in reducing risk factors.

(Response) FDA thanks the AMIF for their comments and appreciates their support in this undertaking.

Regarding the burden estimation, due to the infrequent and nonstandard nature of the questions that may or may not be asked to clarify direct observations made by the Specialists in completing Section 3, parts A and C of the data collection form, only the burden associated with

the information collection related to the completion of Sections 1 and 2 and Section 3, part B of the form is included in burden estimates. For each data collection, the respondents will include the person in charge of the selected facility and the program director (or designated individual) of the respective regulatory authority. In consideration of FMI's comment to the 60-day notice and recent data collection training that was conducted with FDA's National Retail Food Team in September 2012, FDA believes that the original burden that was published in table 3 of the 60-day notice may have been underestimated. For this reason, FDA is increasing the burden estimate for each respondent by 15 minutes per response. For the pilot, 25 Specialists will conduct 4 data collection inspections; thus, FDA estimates the number of respondents to be 200 (25 Specialists x 4 data collection inspections x 2 respondents per data collection). The estimate of the hours per response is based on its previous experience with collecting similar information in previous data collection efforts. We estimate that it will take each of the respondents 30 minutes (0.5 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 100 hours. FDA bases its estimate of the number of respondents during the subsequent activities (data collections) on 400 inspections being conducted in each facility type. FDA CFSAN's Biostatistical Branch has determined that 400 inspections are necessary to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data. The data collections in the Restaurant Segment will occur in 2013, 2016, and 2019 and will each consist of 1,600 respondents. We estimate that it will take each respondent 30 minutes (0.5 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 800 hours. The data collections in the Institutional Foodservice Segment will occur in 2014, 2017, and 2020 and will each consist of 2,400 respondents. We estimate that it will take each respondent 30 minutes (0.5 hours) to answer the

questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 1,200 hours.

The data collections in the Retail Food Store Segment will occur in 2015, 2018, and 2021 and will each consist of 3,200 respondents. We estimate that it will take a respondent 30 minutes (0.5 hours) to answer the questions related to Sections 1 and 2 and Section 3, part B of the form, for a total of 1,600 hours. Thus, the total estimated burden is 10,900 hours.

Table 3.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pilot Data Collection to Practice Use of Form and Methods and Exportation of Data into Central Repository	200	1	200	0.5 (30 minutes)	100
2013 Baseline Data Collection--Restaurant Segment (includes two facility types)	1,600	1	1,600	0.5 (30 minutes)	800
2014 Baseline Data Collection--Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	0.5 (30 minutes)	1,200
2015 Baseline Data Collection--Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.5 (30 minutes)	1,600
2016 Second Data Collection--Restaurant Segment (includes two facility types)	1,600	1	1,600	0.5 (30 minutes)	800
2017 Second Data Collection--Institutional Foodservice Segment (includes three facility types)	2,400	1	2,400	0.5 (30 minutes)	1,200
2018 Second Data Collection--Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.5 (30 minutes)	1,600
2019 Third and Final Data Collection--Restaurant Segment (includes two facility types)	1,600	1	1,600	0.5 (30 minutes)	800
2020 Third and Final Data Collection--Institutional	2,400	1	2,400	0.5 (30 minutes)	1,200

Table 3.--Estimated Annual Reporting Burden¹

Foodservice Segment (includes three facility types)					
2021 Third and Final Data Collection—Retail Food Store Segment (includes four facility types)	3,200	1	3,200	0.5 (30 minutes)	1,600
Total					10,900

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Report of the FDA Retail Food Program Steering Committee, “Database of Foodborne Illness Risk Factors (2000).” Available at:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2001/ucm123544.htm>.

2. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).”

Available at:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorstudies/ucm089696.htm>.

3. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).”

Available at:

<http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/RetailFoodRiskFactorStudies/ucm224682.pdf>.

4. FDA National Retail Food Team, “FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).” Available at:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm223293.htm>.

5. “FDA Food Code.” Available at:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm>.

Dated: October 23, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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